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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,702	08/22/2003	Yanggu Shi	PF398P2D1	9298

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,702	SHI ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 3-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed on 05 November 2005 is acknowledged and entered. Following the amendment, claim 2 is canceled, and the new claim 24 is added.

Currently, claims 1 and 3-24 are pending.

Election/Restrictions

I. Claims 1, 3-19, and claim 23 in part (parts (c)-(e)), drawn to an isolated nucleic acid having SEQ ID NO:1, or encoding SEQ ID NO:2, variants and fragments thereof, a vector containing the nucleic acid, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claim 23 in part (parts (a) and (e)), drawn to an isolated nucleic acid 95% identical to SEQ ID NO:4, classified in class 536, subclass 23.1.

III. Claim 23 in part (parts (b) and (e)), drawn to an isolated nucleic acid 95% identical to SEQ ID NO:5, classified in class 536, subclass 23.1.

IV. Claims 20 and 21, drawn to an isolated polypeptide with SEQ ID NO:2, and a fragment thereof, classified in class 530, subclass 351 and 350.

V. Claim 22, drawn to an isolated antibody, classified in class 530, subclass 387.9.

VI. Claim 24, drawn to a method of diagnosing a disease by contacting a biological sample with the antibody, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

Inventions I-III are distinct each from each other because each of SEQ ID NOs has a unique sequence and represent a distinct chemical entity requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

The nucleic acid of Invention I is related to the polypeptide of Invention IV by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the

protein in a host cell. Although the nucleic acid and the protein are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention IV as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The nucleic acids of Inventions I-III are distinct from and unrelated to the antibody of Invention V because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the antibody of Invention V because the antibody may be neither made by nor used in the method.

Inventions I-III are distinct from and unrelated to Invention VI, wherein the products of Inventions I-III are neither made by nor used in the method of Inventions VI, and wherein each does not require the other.

The nucleic acids of Inventions II and III are distinct from and unrelated to the polypeptide of Invention IV because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The polypeptide of Invention IV is related to the antibody of Invention V by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for

production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention IV is distinct from and unrelated to Invention VI, wherein the product of Invention IV is neither made by nor used in the method of Inventions VI, and wherein each does not require the other.

Invention V is related to Invention VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody as claimed may be used for the purification of the polypeptide of Invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, if group I or IV is elected, further **restriction** is required under 35 U.S.C. 121:

A. If group I is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct nucleic acids, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a nucleic acid, selected from the group consisting of:(i.e. elect one from the following Markush group): a nucleic acid comprising a polynucleotide encoding the polypeptide of SEQ ID NOS:2, **or** a nucleic acid comprising a polynucleotide encoding **one** of the epitope-bearing portions of said polypeptide, as recited in claim 14.

B. If group IV is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group): a polypeptide having an amino acid sequence selected from the group

consisting of the polypeptide of SEQ ID NOS:2, **or one** of the epitope-bearing portions of said polypeptide, as recited in claim 21.

The inventions are distinct, each from the other because of the following reasons:

Although the classifications for these various nucleic acids or polypeptides are overlapping, for instance 536/23.1 or 530/350, each represents a patentably distinct product with distinct physical and functional characteristics. Further, the search for more than one product would be burdensome, because, in the case of the nucleic acid sequences, many are claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO:1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO:2, such that each individual sequence requires two sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid or polypeptide, which requires a separate "word search" of the nucleic acid and protein databases. Due to the use of 'comprising' language, it cannot even be said that the search for nucleic acids encoding amino acids 1-426 of SEQ ID NO:2 would reveal art pertaining to, for instance, a nucleic acid *comprising* a region encoding amino acids 14-22 of SEQ ID NO:2, as the latter could be found embedded in a completely different protein. Accordingly, restriction is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-VI, and an election of the invention from Group A or B, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-VI nor A and B is species election requirement; rather, each of I-VI, A and B is a restriction requirement.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/1/06